doctor. If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a doctor.''

(2) ''This product may cause temporary burning and irritation on being instilled into the eye.''

(3) ''If solution changes color or becomes cloudy, do not use.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'': Instill 1 or 2 drops in the affected eye(s) every 3 or 4 hours, or as directed by a doctor.

§ 349.75 Labeling of ophthalmic vasoconstrictor drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug(s), if any, and identifies the product as a ''redness reliever'' or ''vasoconstrictor (redness reliever)'' (select one of the following: ''eye'' or ''ophthalmic'') ''(insert dosage form, e.g., drops).''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' the following phrase: ''Relieves redness of the eye due to minor eye irritations.''

(c) *Warnings.* In addition to the warnings in § 349.50, the labeling of the product contains the following warnings under the heading ''Warnings'' for products containing any ingredient identified in § 349.18:

(1) ''If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.''

(2) ''If you have glaucoma, do not use this product except under the advice and supervision of a doctor.''

(3) ''Overuse of this product may produce increased redness of the eye.''

(4) ''If solution changes color or becomes cloudy, do not use.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'': Instill 1 to 2 drops in the affected eye(s) up to four times daily.

EFFECTIVE DATE NOTE: At 65 FR 38428, June 21, 2000, § 349.75 was amended by revising paragraph (c)(2) and by adding paragraph (c)(5), effective May 16, 2002. For the convenience of the user, the revised text is set forth as follows.

§ 349.75 Labeling of ophthalmic vasoconstrictor drug products.

* * * * *

(c)

(2) ''Ask a doctor before use if you have [in bold type] narrow angle glaucoma.''

* * * * *

(5) ''When using this product [in bold type] pupils may become enlarged temporarily.''

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§ 349.78 Labeling of eyewash drug products.

(a) *Statement of identity.* The labeling of the product identifies the product with one or more of the following terms: ''eyewash,'' ''eye lotion,'' or ''eye irrigating solution.''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' one of the following phrases:

(1) ''For'' (select one of the following: ''flushing,'' ''irrigating,'' ''cleansing,'' ''washing,'' or ''bathing'') ''the eye to remove'' (select one or more of the following: ''loose foreign material,'' ''air pollutants (smog or pollen),'' or ''chlorinated water'').

(2) ''For'' (select one of the following: ''flushing,'' ''irrigating,'' ''cleansing,'' ''washing,'' or ''bathing'') ''the eye to help relieve'' (select one or more of the following: ''irritation,'' ''discomfort,'' ''burning,'' ''stinging,'' ''smarting,'' or ''itching'') ''by removing'' (select one or more of the following: ''loose foreign material,'' ''air pollutants (smog or pollen),'' or ''chlorinated water'').

(c) *Warnings.* In addition to the warnings in § 349.50, the labeling of the product contains the following warnings under the heading ''Warnings'' for all eyewash products:

(1) ''If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a doctor.''

(2) ''Obtain immediate medical treatment for all open wounds in or near the eyes.''

(3) ''If solution changes color or becomes cloudy, do not use.''